

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO:

*Carol Jean Dimock v. Ethicon, Inc., et al.*

Civil Action No. 2:12-cv-00401

MEMORANDUM OPINION AND ORDER  
(*Daubert* Motion re: Vladimir Iakovlev, M.D.)

Pending before the court is the Motion to Exclude Case Specific Testimony of Vladimir Iakovlev, M.D. [ECF No. 113] filed by the defendants. The Motion is now ripe for consideration because briefing is complete.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file specific causation *Daubert* motions, responses, and replies in the individual member cases. To the extent that an expert is both a general and specific causation expert, the parties were advised that that they could file a general causation motion in the main MDL 2327 and a specific causation motion in an individual member case. PTO No. 217, at 4.

## II. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*,

509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

In the context of specific causation expert opinions, the Fourth Circuit has held that “a reliable differential diagnosis provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999).

A reliable differential diagnosis typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

*Id.* at 262 (citations omitted). “A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.” *Id.* at 265. However, an expert’s causation opinions will not be excluded “because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.” *Id.* “The alternative causes suggested by a defendant ‘affect the weight that the jury should give the expert’s testimony and not the admissibility of that testimony,’ unless the expert can offer ‘no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause.’” *Id.* at 265 (citations omitted).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

### III. Discussion

Ethicon seeks exclusion of Dr. Iakovlev's specific causation opinions. Among other things, Ethicon argues that Dr. Iakovlev did not conduct a proper differential diagnosis. I disagree.

Dr. Iakovlev is an anatomical pathologist who has reviewed over 250 cases of explanted meshes, including approximately 170 transvaginal mesh specimens. Resp. 2–3 [ECF No. 122]. Dr. Iakovlev has also published and presented his findings on mesh and mesh-related issues in a variety of peer-reviewed journals and scientific meetings, respectively. *Id.* Dr. Iakovlev's expert report and deposition testimony show that he conducted a detailed review of the plaintiff's medical records and thoroughly examined specimens of mesh and related tissue taken from the plaintiff. Dr. Iakovlev also considered alternative causes for the plaintiff's injuries and explained his reasons for ruling out those alternative causes.

As discussed above, an expert's causation opinions will not be excluded “because he or she has failed to rule out every possible alternative cause of a plaintiff's illness.” *Westberry*, 178 F.3d. at 265. Ethicon's suggested other possible alternative causes affect the weight—not the admissibility—of an expert's testimony, unless the expert can provide *no* explanation for ruling out such alternative causes at trial. *See id.* at 265. To the extent that Ethicon believes that Dr. Iakovlev failed to properly consider other alternative causes, Ethicon is free to address those issues on cross-

examination.

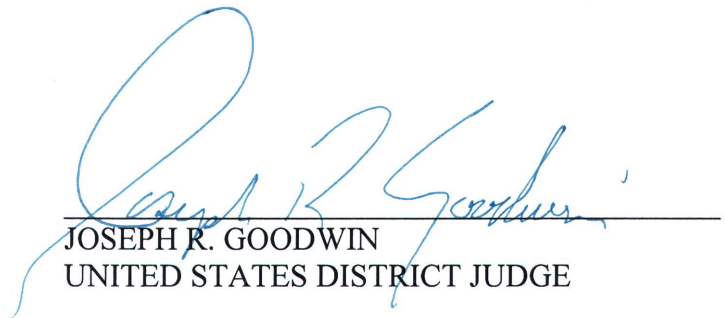
Ethicon's Motion on this point is **DENIED**, and any remaining issues are **RESERVED** for trial.

#### **IV. Conclusion**

The court **DENIES in part** and **RESERVES in part** the Motion to Exclude Case Specific Testimony of Vladimir Iakovlev, M.D. [ECF No. 113].

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: November 28, 2016



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE